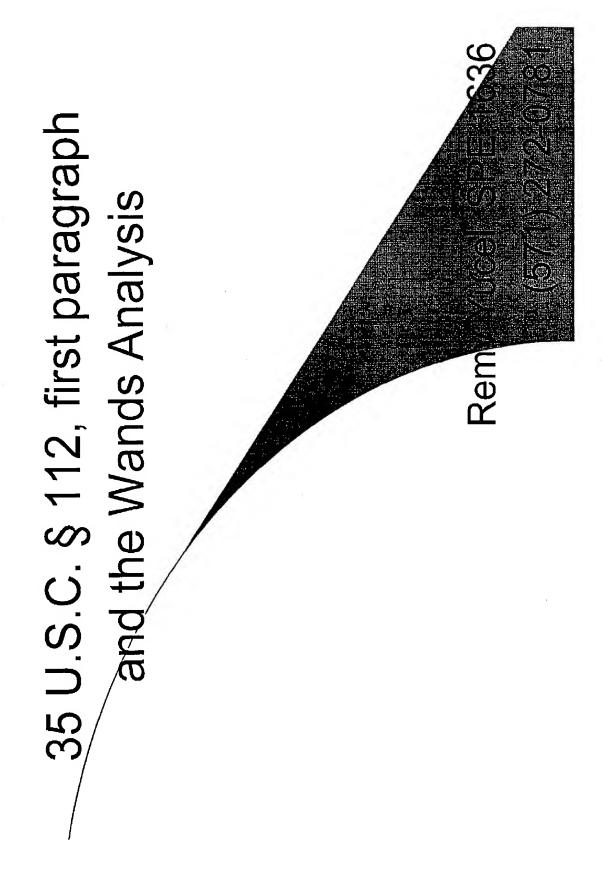
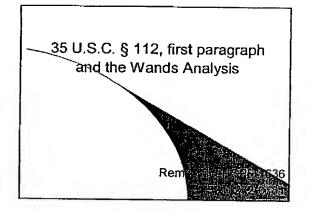
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35 U.S.C. § 112, first paragraph enablement

"The specification shall contain a wiften description of the invention, and of the manner and process of making and using it, in [2] full, clear, concise, and exact terms as to enable and person skilled in the art to which it pertain, gowith which it is most nearly connected, to nearly with which it is most nearly connected, to nearly and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

35 U.S.C. § 112, first paragraph enablement

- "The test of enablement is whether one reasonable skilled in the art could make or use the avention from the disclosures in the patent coupled with information known in the art without undit experimentation."
 - United States v. Telectronics, Inc., 857 F
 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cit 1988)
- A patent need not teach, and preferably omit what is well known in the art.

MPEP § 2164.05

 "In making the determination of enable cot, the examiner shall consider the original discussion and all evidence in the record, weighing evidence that supports enablement against evidence that the specification is not enabling."

Test for Enablement

Intervet Inc.

- Determine of scope of the claimed in antion
- · Ascertain if the teachings in the specific are commensurate in scope such that one skill in the art could practice the invention (its full scope) without undue experimentation

Test for Enablement

- If the statement of utility contains with connotation of how to use, and the art recognizes that standard modes of administration are contemplated, 35 U.S.C is satisfied.
 - -MPEP 2164.01 (c)

For Example

- If one skilled in the art could obtain such Information without undue experiem entation, then it is not necessary to specify the dosage par method of use.
- If one of ordinary skill would be able to discern appropriate dosage or method of use based knowledge of compounds having similar physiological or biological activity without undu experimentation, this will be sufficient to satisfy U.S.C. 112.

If on the other hand....

- The use disclosed is of such nature that the art is unaware of successful treatments with chemically analogous compounds, a more comp statement of how to use must be supplied disclosure.
- The information regarding dosage or method making and using cannot readily be discerned the prior art and the disclosure, then an inquir the level of experimentation necessary to ascel this information is appropriate.

Standard for Enablement

- The standard for determining weether the specification meets the enablement requirement:
 - Is the experimentation needed to practice the invention undue or unreasonable?
 - Supreme Court decision of Mineral Separation
 V. Hyde, 242 U.S. 261, 270 (1916)
 - . M.P.E.P. 2164.01

Undue Experimentation

- The test of enablement is not wheth experimentation is necessary, but whe experimentation is necessary, it is unduced
 - (In re Angstadt, 537 F.2d 498, 504, 190 U 214, 219 (CCPA 1976))

Undue Experimentation

- There are many factors to be considered when determining whether there is sufficient idence to support a determination that a disclosurable not satisfy the enablement requirement as whether any necessary experimentation is "undue."
 - -M.P.E.P. 2164.01

In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)

 The determination that "undue experime would have been needed to make and use claimed invention is not a single, simple fact determination.

Wands Factors

- the nature of the invention
- the state of the prior art
- · the predictability or lack thereof in the
- the amount of direction or guidance pre
- the presence or absence of working example.
- the breadth of the claims
- the relative skill of those in the art
- the quantity of experimentation needed

Undue Experimentation and Enablement

- It is improper to conclude that a disclosure is not enabling based on an analysis of pay one of the above factors while ignoring one discover of the others.
- The examiner's analysis must consider all veldence related to each of these factors, as any conclusion of nonenablement must be based on the evidence as a whole.

Undue Experimentation and Enablement

- A conclusion of lack of enablement peans that, based on the evidence regarding each the above factors, the specification, at the transport properties application was filed, would not have taught skilled in the art how to make and/or use the fill scope of the claimed invention without unduexperimentation.
 - In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Wands Factors

- Provide a framework for analyzing the level of experimentation required of one of skill in the art
- Not all factors are relevant for every explement determination
- Wands Factor format used in Enzo Bioche 11.10
 V. Calgene Inc. (CAFC) 52 USPQ2d 1129 h
 been adopted by the Board of Patent Appeal, and
 Interferences

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Predictability and state of the art and the Enablement Requirement

- The amount of guidance or direction seeded to enable the invention is inversely related the amount of knowledge in the state of the as the predictability in the art.
- The "amount of guidance or direction" refers information in the application, as originally filed that teaches exactly how to make or use the invention.
 - In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CC 1970).

Predictability and state of the art and the Enablement Requirement (con't.)

- The more that is known in the prior art about the nature of the invention, how to make and how to use the invention, and the more predicable the art is, the less information needs to be explicitly stated in the specification.
- In contrast, if little is known in the prior art application. the nature of the invention and the art is unpredictable, the specification would need in detail as to how to make and use the invention order to be enabling. -M.P.E.P. 2164.03

The Enablement Continuum treatment Level or bar for enablement increases

Example A

- Claim 1. A chemical complex having Permula I.
 Claim 2. A pharmaceutical composition comprising the complex of claim 1 and a pharmaceutically acceptable compr.
- Claim 3. A method of lowering the level of X in the method comprising contacting said cell or tissue complex of claim 1 in an amount sufficient to lower the Claim 3. said cell or tissue. (X is a type of oxygen radical)
- Claim 4. A method of treating or preventing a patholog-lowering the level of X in a subject by administering to said in need thereof a therapeutically effective amount of the co claim 1.
- Claim 5. The method of claim 5 wherein said pethology is selected from the group consisting of Abzheimer's disease, stranger, depending autoimmune diseases, cancer, septic shock chronic inflammation and atherosclerosis.

Example A: Facts

- The specification teaches how to make the complex having Formula I.
- The specification contains a single in viltro example in which cells in culture that have been exposed to the complex have lower levels of X relative to control cells.
- The specification does not establish a cause-effect relationship between the level of X and any disease, but teaches that the level of X is associated with pathologies enumerated in claim 5.

Example A: Wands Analysis

- the nature of the invention
- the breadth of the claims
- the state of the prior art
- · the predictability or lack thereof in the
- the amount of direction or guidance present in the specification
- the presence or absence of working examples
- the relative skill of those in the art
- the quantity of experimentation needed

Example A: Wands Analysis

- The nature of the invention is drawn to be treatment and prevention of pathologies through the administration of a chemical complex.
- The breadth of the claims is broad because it encompasses:
 - > both in vitro and in vivo contexts (claims 3-5)
- > both treatment and prevention (claims 4-5)
- > pathologies with vastly different etiologies of unknown etiologies (claim 5)
- > pathologies beyond those in claim 5 (claim 4)

Example A: Wands Analysis

- the nature of the invention
- the breadth of the claims
- the state of the prior art
- · the predictability or lack thereof in the
- the amount of direction or guidance present in the specification
- the presence or absence of working examples
- the relative skill of those in the art
- the quantity of experimentation needed

Example A: Wands Analysis

- · Look to the prior art for:
- > teachings of similar complexes, their role is reducing levels of X and treatment or preven pathologies > the etiologies of the claimed diseases, discern
- shared or are divergent or even known
 information about the levels of X and association v pathologic conditions
- > the level of X causing a disease or a symptom or is downstream effect?
- > the ability to predict that an individual will develop one claimed diseases (Implications for preventative measu

Example A: Wands Analysis

- the nature of the invention
- the breadth of the claims
- the state of the prior art
- the predictability or lack thereof in the
- the amount of direction or guidance present in the specification
- the presence or absence of working examples
- the relative skill of those in the art
- the quantity of experimentation needed

Example A: Wands Analysis

- Look to the specification for:
- > extension of knowledge of the prior art
- > guidance to overcome challeng obstacles, hurdles recognized in
- > working examples: their absence it fatal; however they are a form of teal that could enable the skilled artisan to practice the claimed invention

Example A: Wands Analysis

- the nature of the invention
- the breadth of the claims
- the state of the prior art
- the predictability or lack thereof in the
- the amount of direction or guidance present in the specification
- the presence or absence of working examples
- the relative skill of those in the art
- the quantity of experimentation needed

Example A: Wands Analysis

 The relative skill of those in chemical biological arts is high.

Example A: Wands Analysis

- the nature of the invention
- · the breadth of the claims
- the state of the prior art
- the predictability or lack thereof in the
- the amount of direction or guidance present in the specification
- the presence or absence of working examples
- the relative skill of those in the art
- the quantity of experimentation needed

Example A: Wands Analysis

- The quantity of experimentation will be determined by how well the state of the prior art and its predictability mesh with the teachings of the disclosure.
- If these sources of knowledge available to skilled artisan do not complement each other then the skilled artisan must resort to empiric experimentation to practice the claimed invention, which could be undue (because of the factors discussed above).

Example A. Wands Analysis

- Consideration of all the evidence leads to a determination for enablement

- determination for enablement

 Possibilities for Example A, claims 3-5:

 Claim 3 may only be enabled for in vitro embodiments

 Claims 4-5 may only be enabled for treatment of only those diseases in which there is a cause/effect nexus between the levels and the disease (higher than mere association)

 Claims 4-5 may only be enabled for prevention of those diseases for which the skilled artisan can appropriately identify who will develop the disease in the future.

Page 8